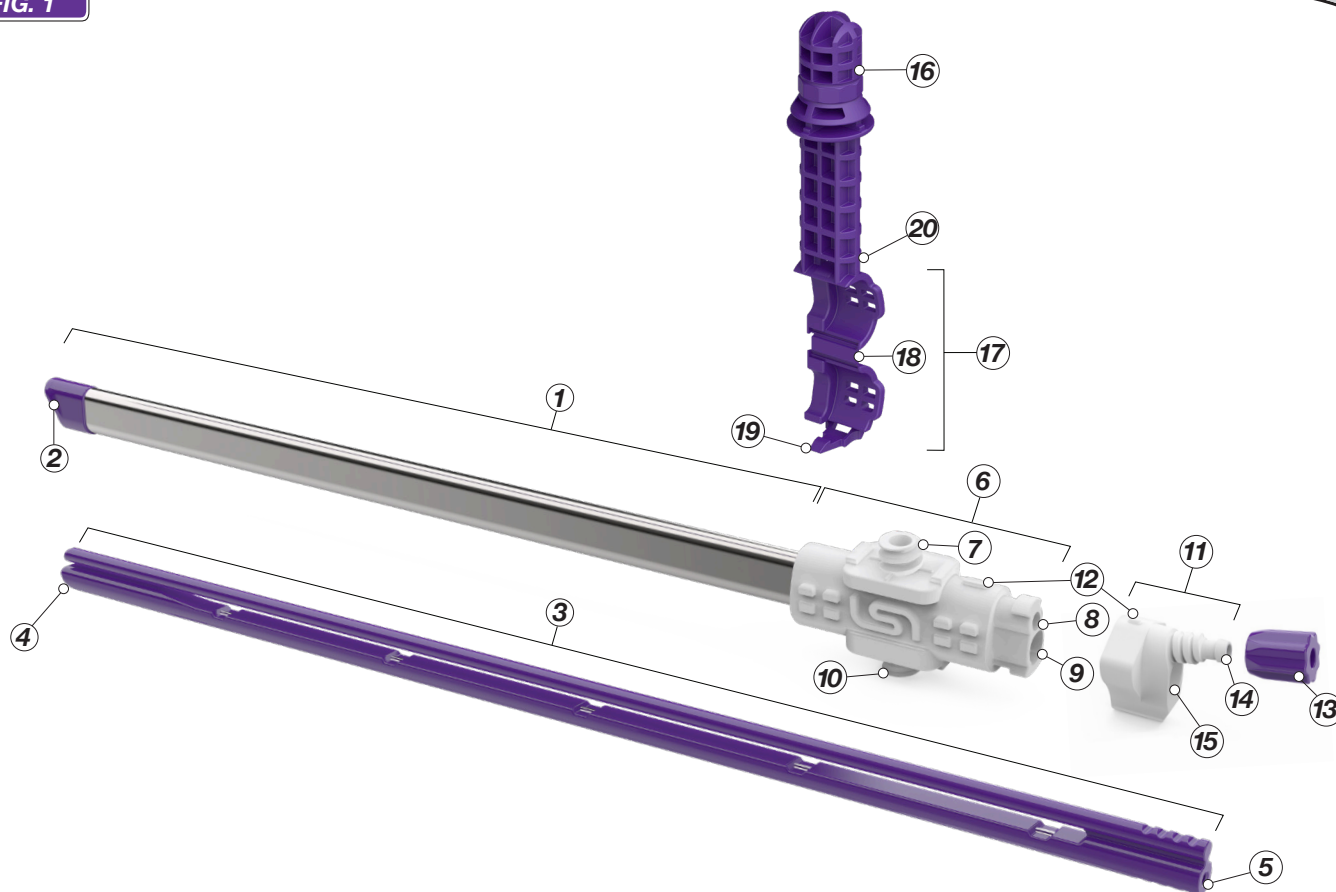


JNW URTRAC® INSTRUMENT GUIDE TECHNOLOGY GUIDE

 READ PRODUCT INSERT THOROUGHLY BEFORE USE

FIG. 1



JNW URTRAC® INSTRUMENT GUIDE

- | | | |
|----------------------|-------------------|-----------------------------|
| ① CANNULA SHEATH | ⑦ UPPER CONNECTOR | ⑫ ROTATIONAL INDICATOR (2X) |
| ② LOW-PROFILE TIP | ⑧ UPPER LUMEN | ⑬ SCOPE LOCK |
| ③ DUAL OBTURATOR | ⑨ LOWER LUMEN | ⑭ 3mm PORT |
| ④ ATRAUMATIC TIP | ⑩ LOWER CONNECTOR | ⑮ 5mm PORT |
| ⑤ GUIDE WIRE CHANNEL | ⑪ ROTATIONAL SEAL | |
| ⑥ TEXTURED HUB GRIP | | |

J-Hold™ multiSTATION™ COUPLER

- | |
|--------------------|
| ⑯ ATTACHMENT SHAFT |
| ⑰ HUB GRIP POCKET |
| ⑱ POCKET HINGE |
| ⑲ POCKET HOOK |
| ⑳ POCKET LATCH |

JNW URTRAC® INSTRUMENT GUIDE DEVICE DESCRIPTION

The JNW URTRAC® INSTRUMENT GUIDE is a sterilized, single-patient-use, dual-lumen cannula and obturator kit. Each kit comprises a dual-lumen cannula sheath, a dual obturator, a rotational seal, a scope lock, and a J-Hold™ multiSTATION™ COUPLER. The seal minimizes fluid loss through the surgeon side of the 3mm and 5mm ports. The J-Hold™ multiSTATION™ COUPLER enables attachment to the multiSTATION™ SYSTEM.

The cannula sheath ① incorporates a low-profile tip ② to facilitate gentle insertion along sensitive tissue. The dual obturator ③ features an atraumatic tip ④ with an integrated guide wire channel ⑤, allowing the assembled cannula with obturator to be inserted over a guide wire. The textured hub grip ⑥ on the surgeon side of the cannula sheath features an upper connector ⑦ for infusing fluid into the surgical site along the upper lumen ⑧, along with a lower lumen ⑨ that facilitates fluid drainage through the lower connector ⑩. With the rotational seal ⑪ connected to the hub grip and the rotational indicators ⑫ on the rotational seal and hub grip aligned, a 3mm endoscope can be passed through the scope lock ⑬ and the cannula using the 3mm port ⑭. The scope lock can be tightened to maintain the endoscope's rotation and axial position or loosened to allow rotation and translation of the scope, as desired. A 5mm instrument can be passed through the cannula using the 5mm port ⑮. To reduce fluid loss, the rotational seal can be rotated clockwise about the upper lumen to close the lower lumen. Note that an instrument cannot be passed through the lower lumen while the rotational seal is rotated to the close position.

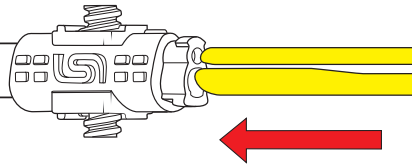
The J-Hold™ multiSTATION™ COUPLER includes an attachment shaft ⑯ for connection to a separately available multiSTATION™ CANNULA ADAPTER. It also includes a hub grip pocket ⑰ into which the JNW hub grip is placed. The pocket hinge ⑱ allows the pocket to wrap around the hub grip such that the pocket hook ⑲ engages with the pocket latch ⑳ (not shown) to secure the coupler in place. The hook and latch can be readily disengaged and reengaged as necessary.

INDICATIONS

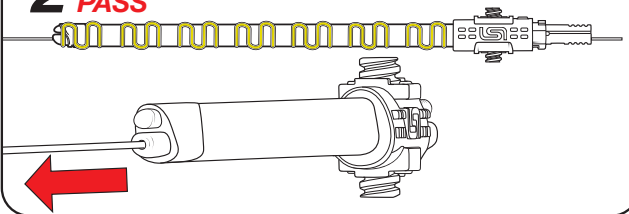
The JNW URTRAC® INSTRUMENT GUIDE is indicated for use as a dual-lumen multipurpose cannula.

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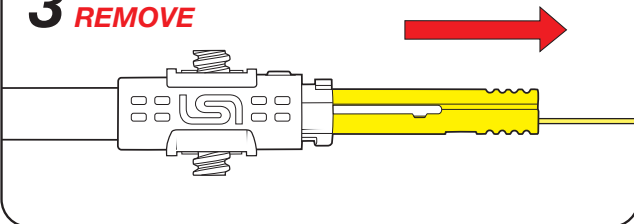
1 INSERT



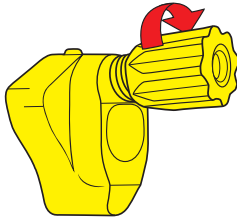
2 PASS



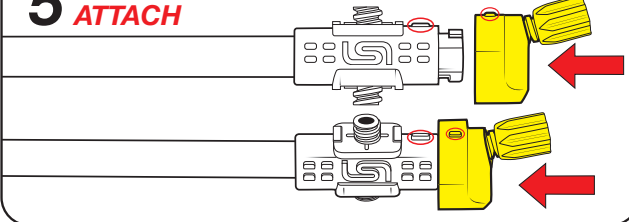
3 REMOVE



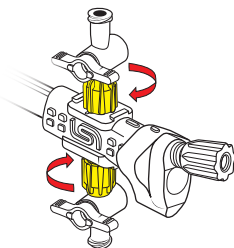
4 THREAD



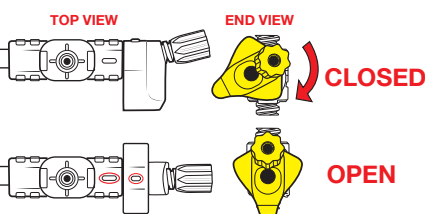
5 ATTACH



6 CONNECT



7 ROTATE



1. **INSERT** the dual obturator into the cannula sheath.

2. **PASS** the dual obturator and cannula sheath into the surgical site.

NOTE: The dual obturator and cannula sheath may be advanced to the surgical site over a guide wire using the guide wire channel. (Optional guide wire shown.)

NOTE: Use standard dilation technique and apply lubrication as needed to facilitate gentle device insertion.

3. **REMOVE** the dual obturator and the guide wire from the cannula sheath when the cannula is positioned at the desired surgical site.

4. **THREAD** the scope lock clockwise to the rotational seal.

NOTE: Partially thread lock to allow for subsequent endoscope insertion.

5. **ATTACH** the rotational seal to the surgeon end of the cannula sheath. Ensure that the indicators at the top of the rotational seal and cannula sheath are properly aligned.

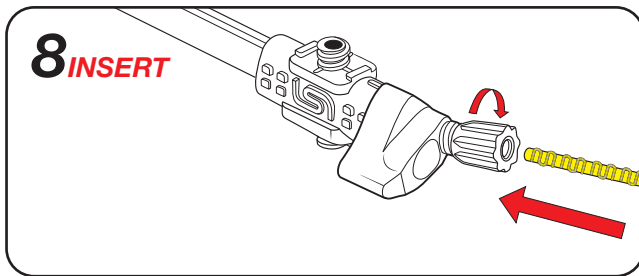
6a. **CONNECT** a stopcock with a fluid source to the upper connector of the cannula sheath if desired.

6b. **CONNECT** a stopcock for drainage to the lower connector of the cannula sheath if desired.

NOTE: Fluid connectors not shown in subsequent images for simplicity.

7. **ROTATE** the rotational seal clockwise to restrict the flow of fluid from the 5mm port as needed.

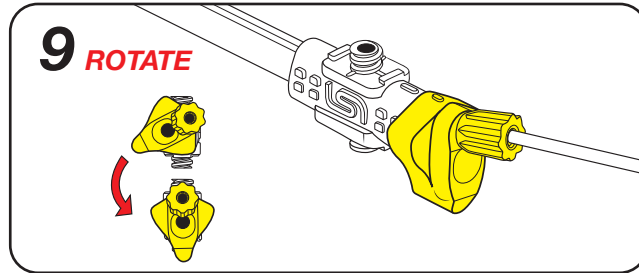
NOTE: Reference the rotational indicators at the top of the rotational seal and cannula sheath to determine whether the seal is opened or closed.



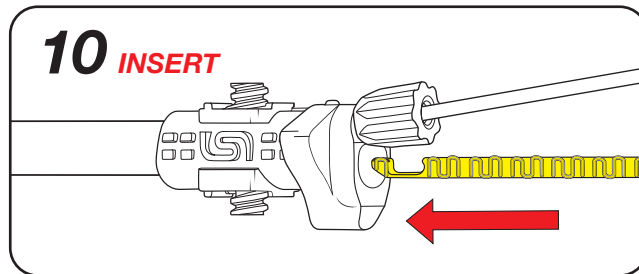
8. **INSERT** the desired scope through the 3mm port of the cannula sheath.

NOTE: Apply lubrication as needed to facilitate scope insertion.

NOTE: DO NOT force the scope through the rotational seal. The 3mm port is intended for a 3mm scope. If excessive resistance is encountered, remove the scope immediately to prevent damage to the scope. Tighten the scope in place by holding the rotational seal and rotating the scope lock clockwise.



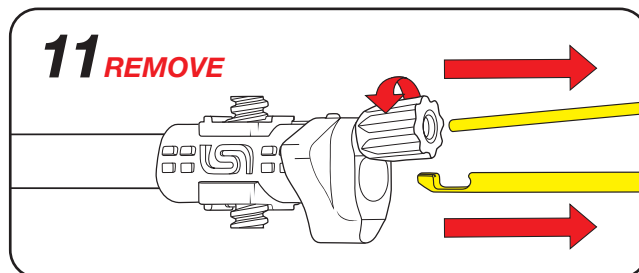
9. **ROTATE** the rotational seal counter-clockwise using the scope as a rotational center to access the 5mm port of the cannula sheath.



10. **INSERT** the desired device through the 5mm port of the cannula sheath. Utilize, adjust, and interchange devices through the 5mm port as needed.

NOTE: Apply lubrication as needed to facilitate device insertion.

NOTE: DO NOT force the device through the rotational seal. The 5mm port is intended to accommodate a 5mm device. Immediately remove the device from the cannula sheath if excessive resistance is encountered during insertion.

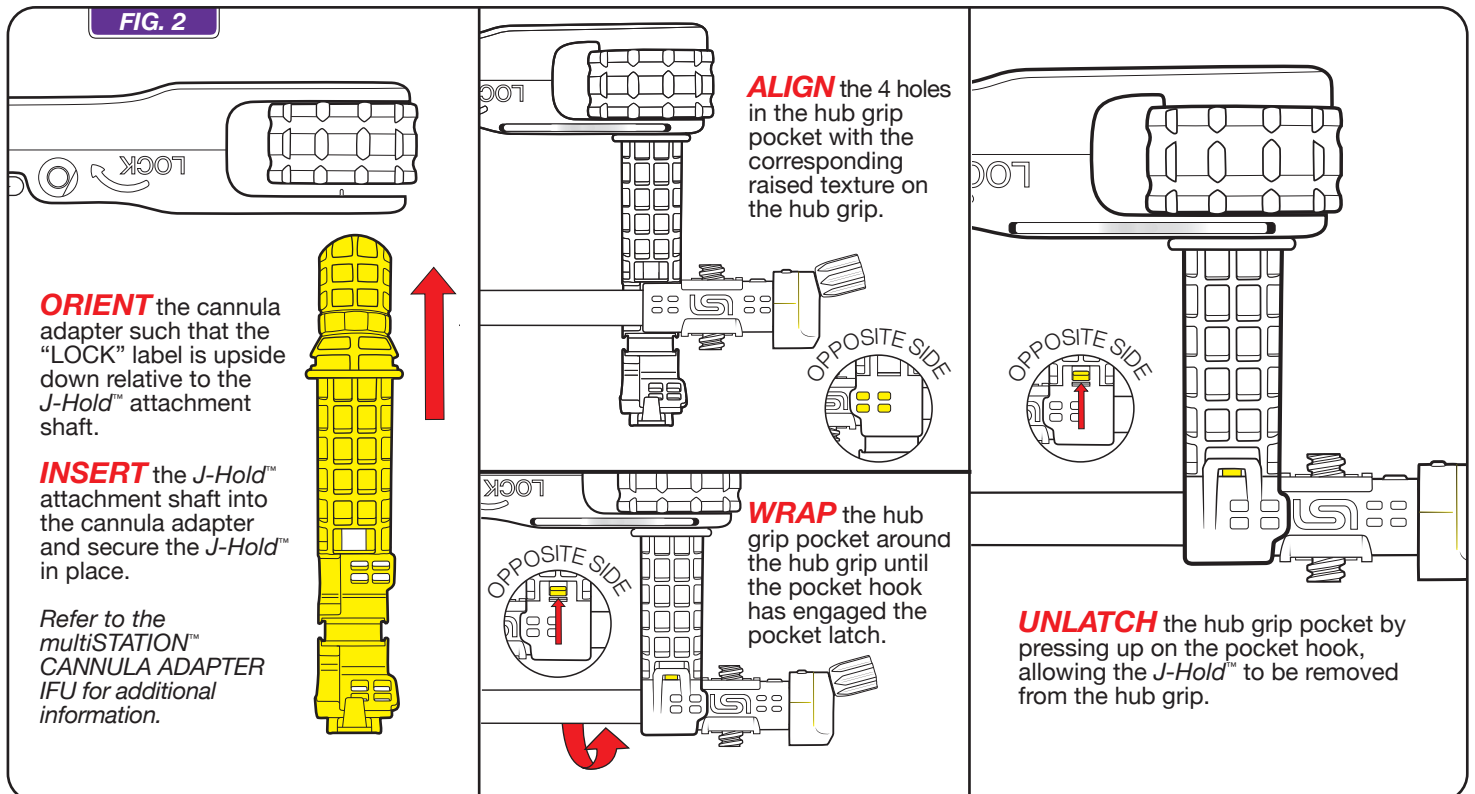


11. **REMOVE** the 5mm device and scope from the cannula sheath following the completion of the procedure.

NOTE: Loosen the scope by rotating the scope lock counter-clockwise.

NOTE: Gently remove the cannula sheath from the surgical site after this step.

Using the J-HOLD™ multiSTATION® COUPLER (optional, sold separately)



ACTIONS:

- The JNW URTRAC® INSTRUMENT GUIDE is a Cannula/Coupler device that provides for ergonomic and repeatable simultaneous use of a 5mm diameter shafted device and 3mm diameter scope. The device is designed as an instrument guide to establish 2 independent lumens: 1 for the passage of scope and inflow of fluid with luer fitting, 1 for the passage of a device and out-flow of fluid with luer fitting.

CONTRAINDICATIONS:

- The JNW URTRAC® INSTRUMENT GUIDE is contraindicated for use under conditions that, in the surgeon's judgement, create unacceptable risk of patient injury during placement, use, and/or removal.
- The JNW URTRAC® INSTRUMENT GUIDE is not intended for use in patients who are contraindicated for retrograde urological procedures.
- The JNW URTRAC® INSTRUMENT GUIDE is contraindicated for use in patients who have the presence of tight strictures precluding passage of the device.
- The JNW URTRAC® INSTRUMENT GUIDE is contraindicated for use in patients who have the presence of large obstructing distal ureteral calculi.

WARNINGS:

- Federal (U.S.A.) law restricts this device to sale, distribution, and use by, or on, the order of a physician.
- Read all instruction manuals thoroughly. Before use, read these instructions and review the manuals/instructions for all other equipment that will be used during the procedure. Inadequate understanding of the techniques, complications, and hazards of surgical procedures can lead to patient harm or death.
- Users should be familiar with standard procedures and techniques for urologic procedures employing the JNW URTRAC® INSTRUMENT GUIDE.
- Applications other than for urologic procedures can result in damage to the JNW URTRAC® INSTRUMENT GUIDE, rendering it unsuitable for continued use.
- During urologic procedures, exposure of open blood vessels to certain pressure conditions can lead to irrigation fluid being absorbed into the circulatory system, potentially resulting in water intoxication of the patient. Water intoxication can lead to patient injury, illness, or death.
- Failure to use nonconductive lubricant, nonconductive distension medium, and nonconductive irrigation fluid can potentially result in patient injury due to high-frequency current.
- Do not reuse, reprocess, or re-sterilize this product. The JNW URTRAC® INSTRUMENT GUIDE is designed and intended for single patient use only. The performance of this product after cleaning or other reprocessing has not been validated and is not supported by LSI SOLUTIONS®. Reuse, reprocessing, or re-sterilization may compromise the integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.
- Discard any opened (unsealed), unused, expired, or damaged JNW URTRAC® INSTRUMENT GUIDE.
- Each JNW URTRAC® INSTRUMENT GUIDE, along with packaging, must be inspected, handled, and disposed of consistent with standard, accepted medical device disposal procedures.
- The JNW URTRAC® INSTRUMENT GUIDE is not insulated against any electrical voltage. When using electrosurgical device techniques, avoid contacting the JNW URTRAC® INSTRUMENT GUIDE with all electrosurgical devices.

PRECAUTIONS:

- Surgical procedures should only be performed by physicians having adequate training and familiarity with such techniques. In addition, medical literature should be consulted relative to techniques, complications, and hazards prior to the performance of surgical procedures. Inappropriate actions or use can lead to patient harm or death.
- Before instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility and ensure that electrical isolation or grounding are not compromised.
- Allowing irrigation fluid to reach temperatures of 43° C / 109° F can result in patient injury. Do not preheat the irrigation fluid above body temperature (37° C / 99° F).
- Do not forcibly advance or withdraw the device if resistance is encountered. If it becomes difficult to advance or withdraw the device, stop its motion and determine the cause of the resistance.
- Care must be taken when moving the multiSTATION™ CANNULA ADAPTER while the JNW URTRAC® INSTRUMENT GUIDE is inserted in the patient.

ADVERSE REACTIONS:

- No documented adverse reactions.

FIG. 3 JNW URTRAC® INSTRUMENT GUIDE PRODUCT ORDERING			SUPPLIED: STERILE
	REORDER	PRODUCT	DESCRIPTION
 x 6	REF 081300	JNW URTRAC® INSTRUMENT GUIDE	Box of 6 Kits (1 Cannula Sheath per Kit) (1 Obturator per Kit) (1 Rotational Seal per Kit) (1 Scope Lock per Kit) (1 J-Hold™ per Kit)
	REF 080415	multiSTATION™ CANNULA ADAPTER	(1 CANNULA ADAPTER per Kit)
 x 6	REF 021100	RD360 PLUS™ DEVICE, (0.046" needle diameter, 33cm length)	Box of 6 Kits (1 Device per Kit)
 x 6	REF 021000	RD360™ DEVICE, (0.036" needle diameter, 33cm length)	Box of 6 Kits (1 Device per Kit)

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Patents: www.lsisolutions.com/patents

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Symbol Glossary: www.lsisolutions.com/symbols



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